UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,783	02/28/2002	Choong-Chin Liew	4231/2002	8718

29933 7590 07/09/2004

PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
LEE, MATTHEW C	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,783	LIEW ET AL.	
	Examiner	Art Unit	
	Matthew C Lee	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to isolated nucleic acid sequences, a vector comprising said sequences and a host cell comprising said vector, classified in class 536, subclass 23.1.

II. Claim 4, drawn to a composition comprising one or more chondrocyte enriched or chondrocyte-specific nucleic acid sequences, classified in class 536, subclass 23.5

III. Claim 5, drawn to a composition comprising nucleic acid sequences selected form Figure 14 drawn as identified in Figure 6B, classified in class 536, subclass 23.1

IV. Claim 6, drawn to a composition comprising nucleic acid sequences selected form Figure 14 as identified in Figure 6C, classified in class 536, subclass 23.1

V. Claim 7, drawn to a composition comprising nucleic acid sequences selected form Figure 14 as identified in Figure 6D, classified in class 536, subclass 23.1

VI. Claim 8, drawn to a composition comprising nucleic acid sequences selected form Figure 14 as identified in Figure 6E, classified in class 536, subclass 23.1

VII. Claim 9, drawn to a composition comprising nucleic acids selected form Figure 14 as identified in Figure 14, classified in class 536, subclass 23.1

VIII. Claims 10-19, drawn to a composition comprising nucleic acid sequences containing at least one differentially expressed sequence, classified in class 536, subclass 23.5.

IX. Claim 11, drawn to a composition comprising nucleic acid sequences containing at least one differentially expressed sequence isolated from patient with severe osteoarthritis relative to normal individual.

X. Claim 20, drawn to a composition comprising nucleic acid sequences identified in Figure 9, classified in class 536, subclass 23.1

XI. Claim 21, drawn to a composition comprising nucleic acid sequences identified in Figure 11, classified in class 536, subclass 23.1

XII. Claim 22, drawn to a composition comprising nucleic acid sequences corresponding to the genes disclosed in Figure 15 and 16, classified in class 536, subclass 23.1

XIII. Claim 23, drawn to a composition comprising nucleic acid sequences corresponding to the genes disclosed in Figure 6, classified in class 536, subclass 23.1

XIV. Claim 24, drawn to a composition comprising nucleic acid sequences disclosed in Figure 13, classified in class 536, subclass 23.1

XV. Claims 25-35 and 57, drawn to an array comprising nucleic acid sequences, classified in class 536, subclass 24.31.

XVI. Claims 36-44, drawn to methods of diagnosing osteoarthritis, classified in class 436, subclass 6

XVII. Claim 45, drawn to a method of identifying an agent that increases or decreases the expression of a nucleic acid sequence, classified in class 436, subclass 6

XVIII. Claims 46-52, drawn to methods of preparing a chondrocyte cDNA library, classified in class 435, subclass 69.1

XIX. Claims 53-56, drawn to a method of making arrays, classified in class 536, subclass 24.31

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups I-XIV each recites a different chemical composition comprising different nucleic acid sequences. The nucleic acid sequence of each Group is a biochemical structure different from the structure of the sequence claimed in any other Group, with different properties, and would be expected to behave differently.

Invention XV is unrelated to any of Inventions I-XIV. Any array is necessarily a different product/structure than a single nucleic acid sequence, with different biochemical properties. An array would be expected to behave differently and to have different functions than a single sequence, thus Invention XV is patentably distinct from all of Inventions I-XIV.

Invention XVI is unrelated to inventions I-XIV. In this instant case, the products of I-XIV and the method of XVI are not disclosed as capable of being used together.

Invention XV is related to invention XVI and XVII as product and processes of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of invention XV is patentably distinct from the method of XVI and XVII because the product can be used to practice either the method of XVI or XVII or methods other than XVI and XVII, for example, invention XV can be used to assay biological samples form non-human species for comparative study. Furthermore, the method of XVI and XVII can also be practiced with hybridization assays in non-array format.

Invention XV is unrelated to invention XVIII. The product of XV and the method of XVIII are not disclosed as capable of being used together.

Inventions XV and XIX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group XV can be make by another materially different process such as *in situ* manufacturing process that does not require spotting or photolithographic method.

Invention XVI is also unrelated to invention XVII, XVIII and XIX. The methods of XVII, XVIII, and XIX each recite different method steps, different mode of operation and different effects from that of invention XVI.

Invention XVII is unrelated to inventions I-XIV. In this instant case, the products of I-XIV are not limited to be those for assay in the method of Group XVII, and the method of Group XVII is not limited to use the products of Groups I-XIV.

Invention XVII is also unrelated to inventions XVIII and XIX. In this instant case, the methods of XVIII and XIX each recites different method steps, has different modes of operation and achieves different effects than the method of XVII.

Invention XVIII is unrelated to inventions I-XIV. In this instant case, the products of I-XIV and the method of XVII are not disclosed as capable of being used together.

Invention XVIII is also unrelated to invention XIX. In this instant case, the methods of XVIII and XIX each recites different method steps, has different modes of operation and achieves different effects.

Invention XIX is unrelated to inventions I-XIV. In this instant case, the products of I-XIV and the method of XIX are not disclosed as capable of being used together.

Sequence Election Requirement Applicable to All Groups

In addition, groups I-XV read on patentably distinct Groups drawn to multiple sequences/SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected

Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement as applied to groups I-XIV, not an election of species. As applied to group XV, directed to a combination of sequences, this requirement is considered an election of species for purposes of facilitating search and examination.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew C Lee whose telephone number is (571) 272-2931. The examiner can normally be reached on 9am - 4:30pm, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P WOODWARD can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew C. Lee
6/24/2004

MARJORIE MORAN
PATENT EXAMINER
6/28/04